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Inventor:	Richard E. Ward	April 15, 2005	APR 15 2005
Serial No.	09/427,149	Group Art Unit: 3623	
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Title:	Automated Care Process Management System	Atty Docket No.: 073618 0259567	Client Ref: RHS-001

RULE 132 DECLARATION BY RICHARD E. WARD

I, Richard E. Ward, MD, MBA, having an address at 242 Pine Street, Windsor, Ontario, Canada, attest as follows:

1. Subject Matter of the Declaration

I am the sole inventor of the subject matter disclosed and claimed in U.S. Patent Application No. 09/427,149.

2. Qualifications as an Expert in the Field

My professional background has allowed me to develop expertise in the field of health care information technology, and in particular the fields of electronic medical record systems, structured documentation systems, and care process management.

- I was trained as a medical doctor (MD), which enabled me to develop expertise in the concepts and terminology commonly used in the process of creating, accessing and using medical information, including medical records, care plans and medical orders.
- I spent seven years (1990-1997) at the Henry Ford Health System, an organization in Southeast Michigan which includes a large, multi-specialty medical group

practice, a network of health care facilities including a large teaching hospital, and a health maintenance organization (HMO). At Henry Ford, I served a number of roles. As Director of the Center for Clinical Effectiveness, I was involved in numerous projects to improve medical processes. Many of these processes involved the processes of acquiring clinical data and the use of clinical data in electronic systems. As Chief of Medical Informatics, I led the process of developing the organization's strategic plan for health care information technology. In this capacity, I was involved in the design and development of software used to acquire structured clinical information from physicians and patients and to manage care processes. I was also involved in the systematic review and evaluation of vendor-supported software applications, including electronic medical record software, clinical documentation software and workflow automation software.

- I spent 2.5 years (1997-1999) at Oceania, Inc., a health care information technology vendor in Palo Alto, California, where I served as Director of Product Management and as Vice President and General Manager for Health Care Organization Products. Oceania was a cutting-edge vendor that developed electronic medical record software with an emphasis on clinical documentation capabilities (also known as "template charting"). In my work at Oceania, I became aware of the capabilities of existing health care software applications, and in particular applications involving clinical documentation, care planning, and care process management. Through my work at Oceania, I was familiar with the software products offered by Araxsys (which was based on the invention described in the Macrae patent) and by Health Hero Network (which was based on the invention described in the Brown patent). Through my work at Oceania, I also conducted formal and informal research to understand the unmet needs of health care providers, including their unmet needs for clinical documentation, care planning and care process management.
- In 1999, I founded and continue to serve as CEO of Reward Health Sciences, Inc. a health care consultancy and software developer that specializes in the application of health care information technology to improving the effectiveness

of care processes. In this capacity, I conducted more research regarding the capabilities of existing health care information technologies and the unmet needs of health care providers and provider organizations. I also spent 4 months of focused research, design and development effort to arrive at the design of the Automated Care Process Management System (ACPMS) described in the patent application that is the subject of this declaration.

3. Background

In the field of clinical medicine, clinicians traditionally write medical "notes" in a "medical record" maintained on paper for each patient. Such medical notes traditionally are organized into sections such as "history of the present illness", "past medical history", "physical examination" and "plan of care". In a traditional clinical note, the plan of care section includes a list of medications, tests and other services to be ordered for the patient, but it does not explain the detailed steps of the process of executing those orders. For example, the plan of care may describe a particular type of X-ray test to be ordered for the patient, but it would not describe the steps of scheduling, taking the X-ray, interpreting the results, preparing a report, delivering a report to the ordering physician, responding to a delayed report, etc.

It is a long-established practice to assist in the capture of complete information in medical notes through the use of "templates". For example, many health care institutions create pre-printed forms for physical examinations, and many operating rooms have pre-printed sheets of paper containing a standard plan of care with post-operative orders. It is also a long-established practice to use computer software to create an electronic version of such templates, such is with "clinical documentation" or "template charting" features of electronic medical record systems and "order sets" within electronic medical order entry systems. Examples of such systems include the Wave system developed by Oceania, Inc. during the early 1990's, and the electronic medical record application developed by Purkinje during approximately the same time period.

Outside of the field of clinical medicine, the concept of "workflow automation software" was well-established before 1999. At that time, such software was already widely available from many vendors, and was being used in diverse settings such as for insurance claim adjudication, telephone service order provisioning, and for many other administrative processes. In such software, the user creates a "workflow process specification" that takes for the form of an electronic process flow diagram consisting of "nodes" displayed as graphical icons representing the steps of a process. These nodes are connected by arrows representing the sequence in which the steps are to be executed. Existing workflow systems allow users to adapt a previously-prepared generic workflow template to the particular needs of a customer. In such systems, the user selects a generic workflow template, views this template as a process flow diagram on a computer display, and manipulates the various icons and arrows on the screen as needed to adapt the diagram to the needs of a particular customer. An example of such a system is the InConcert system, developed during the early 1990's and subsequently acquired by TIBCO.

4. The Macrae Patent

To my knowledge, Macrae was among the first to recognize the potential application of workflow automation software technology to the process of creating and executing a plan of care for a patient. However, in my opinion, Macrae chose to apply this workflow automation technology in a way that was not feasible for clinicians. In his patent #5,826,237 (the "'237 patent"), Macrae described a process of creating a care plan where the care plan itself is in the form of an electronic workflow process flow diagram. He describes specific types of "nodes" relevant to clinical medicine, including an "order node" that contains data about health care services planned for a patient and a "result node" that corresponds to the process step of capturing the data for the results of previously ordered tests such as laboratory tests. Macrae described a method whereby clinicians routinely use the system in a clinic setting as part of the process of caring for patients. In the '237 patent, Macrae described the method to be used by such clinicians to select a previously-created care plan template relevant to the problems and needs of a

particular patient, to customize such a generic template to better suit the needs of the particular patient, and to merge the resulting plan with the existing "master plan" for the patient. Macrae described in detail the process steps of customizing the generic template, including "adding nodes, deleting nodes, or modifying node contents in a Flow Chart view."(Column 21, Lines 7-12). Macrae also described in detail the process steps of merging health care plans. For example, in Column 23, lines 33-45, Macrae described the process of merging a wrist trauma plan with a hip replacement plan as follows:

"Before a user can merge the wrist plan into the active hip plan, a user needs to move the wrist nodes to day four where the hip plan is presently active. Select the Order Node in the first triplet in the wrist plan and choose Select All Nodes Right from the Edit menu. This selects all of the wrist plan nodes. Now, drag the nodes to the right until the first triplet is positioned in day four and the second set of triplets is positioned in day five. Next, scroll the hip plan to the right until both plans are aligned by time slot. Adjust the scrolling so that a user can see all of day four and five. When a user is done, the Flow Chart view window looks similar to FIG 44."

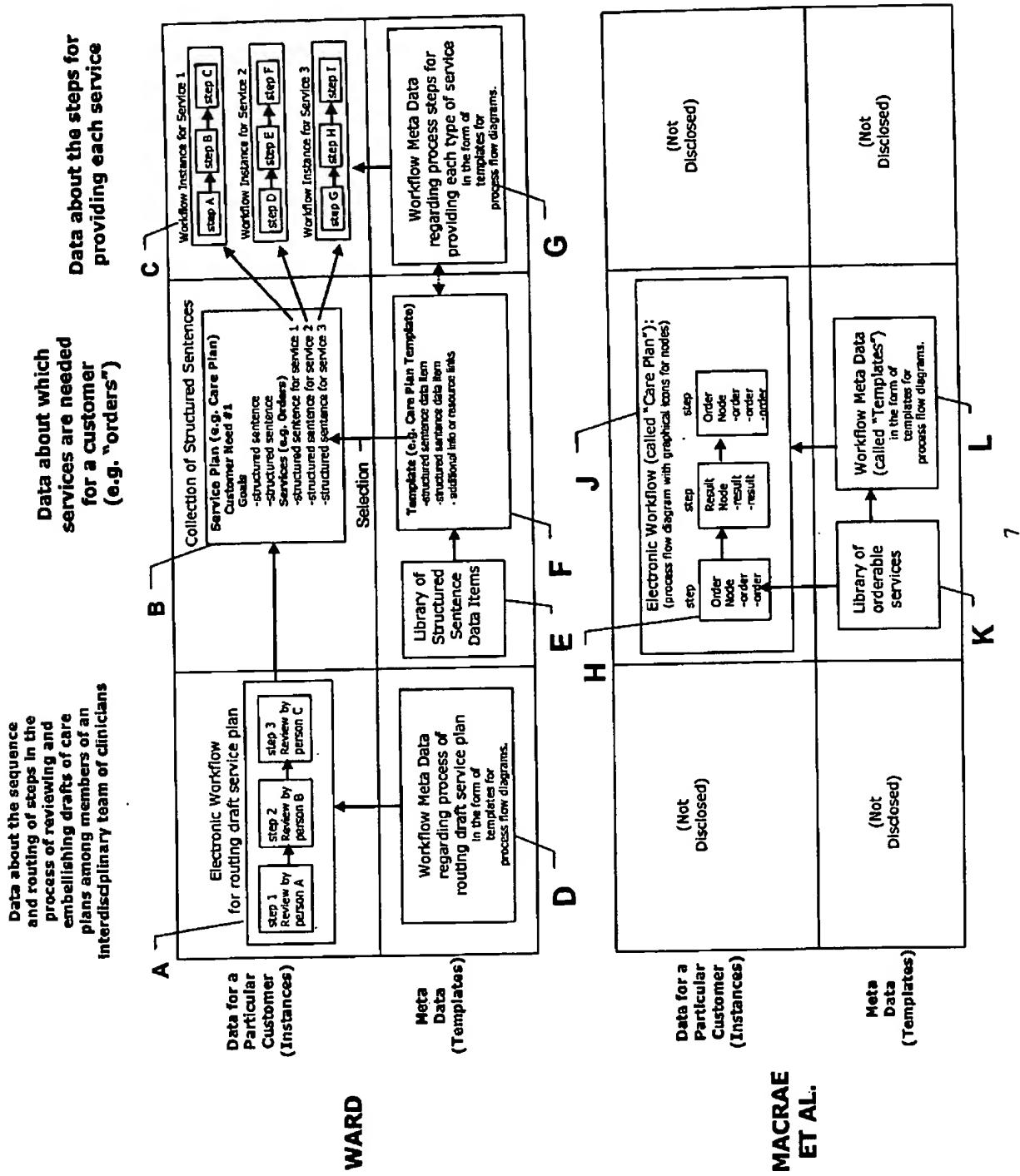
FIG 44 shows a diagram of a computer screen with process flow diagrams showing the workflow. The key point is that the invention described in the '237 patent requires clinicians to directly view and manipulate electronic workflow process flow diagrams on a computer display as a routine part of the process of caring for patients. It is my opinion that such a process is far too tedious to be tolerated by busy clinicians in hectic clinical settings. It is also apparent that by representing the plan of care as a process flow diagram, the system would be quite unfamiliar to clinicians who are used to having the plan of care represented as textual sentences within a clinical note, together with other sections containing text for "history of present illness", "past medical history" "physical examination", etc. The invention described in the '237 patent was developed and marketed as a commercial software product during the late 1990's by Araxsys, Inc. (which subsequently was renamed to Confer and later acquired by Quovodx). This commercial software product was marketed as a tool for use in clinics for patient care,

but I do not believe it was commercially successful. At the time, I was employed as Director of Product Management for Oceania, Inc., another clinical software vendor, so I was familiar with the product and its reception by the medical community. In my opinion, a primary reason for the commercial failure of this product in clinic settings was the fact that it was perceived by clinicians to be too unfamiliar and tedious to use.

5. The Automated Care Process Management System (ACPMS)

The Automated Care Process Management System (ACPMS) described in patent application 09/427,149 has a number of things in common with the invention described by Macrae. For purposes of comparing and contrasting ACPMS with Macrae, which is a health care application, I will discuss the ACPMS in the context of an embodiment in the health care field, though it also applies to other embodiments.

Both Macrae and ACPMS are intended to use information technology to improve the process of creating and executing care plans, both recognize the importance of assisting in the creation of complete care plans through the use of previously-prepared templates, and both incorporate the concepts of workflow automation software technology. However, I recognize numerous and essential differences between the two, as would any other person of ordinary skill in the healthcare information technology industry. These essential differences are illustrated in the following figure:



As shown in this figure, both inventions include a process for creating and using data about which services are needed for a customer. In the health care context, this corresponds to data about which services are *ordered* for a *patient*. However, Macrae represents this information in the form of an electronic workflow process flow diagram, while the ACPMS does not attempt to represent the care plan as a workflow process flow diagram. Rather, the ACPMS represents the entire note, including the plan of care section, as a collection of structured sentences which are entered, manipulated and displayed to the user on the screen with the appearance of essentially grammatically-correct textual sentences, such that the document resembles to the user the familiar form of a textual document. Like Macrae, ACPMS assists in the creation of a complete plan of care through the use of previously-prepared templates. However, the templates described by Macrae are in the form of electronic workflow process flow diagrams (with icons and arrows), while the structured sentence templates used by ACPMS are in the form of a collection of structured sentences (i.e. with no icons and arrows to be repositioned, edited and otherwise manipulated during busy clinic sessions).

ACPMS incorporates workflow automation technology for two different purposes, neither of which was anticipated by Macrae. First, as shown at label "A" in the figure, ACPMS uses workflow automation technology to sequentially route a care plan that has been drafted for a particular patient to each of the various clinicians that are involved in the care of that patient so that each of these clinicians can review and revise the care plan to enhance the comprehensiveness of the care plan and to improve coordination of care. Second, as shown at label "C" in the figure, once the care plan has been finalized and electronically signed, ACPMS creates a separate workflow process instance for each of the orders in the care plan (each order being represented by a structured sentence for service). Each of these process instances is created based on a previously-prepared workflow template that defines the steps required to carry out that particular type of order. Note that this use of workflow, shown at label "C", is not equivalent to the use of workflow by Macrae, shown at label J. Macrae described the use of a single workflow instance to define a care plan that may contain multiple orders, while the ACPMS uses separate workflow instances for each order. In Macrae, the arrows connecting the steps

(nodes) within the workflow process flow diagram are defining the sequence that orders are to be carried out. In contrast, in ACPMS, the arrows connecting the steps in the workflows process flow diagram shown at label C are defining the sequence of steps to carry out a single order. Any person of ordinary skill in the field of health care information technology would recognize that an order is not equivalent to a step in the process of carrying out an order. One skilled in the art would recognize that these are not subtle differences, but rather they are fundamental, essential differences.

Furthermore, ACPMS combines these innovations in the process of creating and executing care plans for individual patients with many additional innovations intended to improve the care for the whole population of patients, two of which I will comment upon here. Neither of these two additional innovations are mentioned anywhere in Macrae or in any of the other patents referenced by the Examiner. The first of these additional innovations involves the automated analysis of data for a population of patients to identify the subset of patients with a particular need and then enabling the automated addition of an order for the needed service to the care plans for each of the selected patients.

The second of these additional innovations involves the gathering of data about the usefulness of clinical alerts so as to inform the process of ongoing improvements of the alerts themselves. According to this second innovation, the workflow instances used to manage the process of executing particular orders may contain logic and content for clinical alert messages to be presented to the clinician. For example, an alert message may contain advice for follow-up to an abnormal laboratory test result. ACPMS presents such alert messages to the user through a user interface designed to capture the clinician's feedback about the appropriateness and usefulness of that alert. Based on my experience, such alert capabilities are not always popular with clinician users because they feel that some of the alerts are useless and bothersome. As a result, some clinician users can develop a habit of ignoring all alerts, leading them to miss out on the important information contained in some of the alerts. Therefore, the statistical summarization of

alert feedback data would be an important source of information to identify alerts with firing logic or message text in need of revision or deletion.

6. Analysis of Examiner's Rejection of Claim 1, 3, 30 and 41

In the Detailed Action dated October, 2004, the Examiner rejected claims 1, 3, 30 and 41 as being anticipated by the Macrae patent. In claim 1, the step of creating a service plan includes the limitation that this service plan includes "structured sentences for services". In claim 1, the step of creating the electronic workflow includes a limitation that such electronic workflow be "in addition to the service plan" and that this step includes the step of "using each structured sentence for service to create a workflow process instance for each needed service." It is my understanding that this means that the Examiner believed that each of these elements (and every other element in the claim) is found identically in Macrae. It is my understanding that the Examiner, in rejecting claims 1, 3, 30 and 41, took the position that:

1. The data for an order in one of Macrae's "order nodes" is equivalent to a structured sentence for service in a care plan.
2. Macrae's concept of "order node" exists separately from Macrae's concept of workflow,
3. Macrae anticipates the creation of a separate electronic workflows for each "order"
4. Macrae's concept of "service plan" exists separately from Macrae's concept of workflow

However, one skilled in the art, upon careful reading of relevant documents, would recognize that none of these positions are accurate.

Regarding the first of these, the assertion that the data for an order in Macrae's order nodes is equivalent to structured sentences for service, the Examiner interprets Macrae as follows (top of page 28):

“Within this template are order nodes that are structured sentences for service, such as orders for vitals, strep tests, etc. These orders contain subjects (vitals) and attributes (temperature, pulse, etc.).”

However, the fact that a data structure includes a subject and attributes is not sufficient for a person skilled in the art to describe the data structure as a “structured sentence.” One skilled in the art would recognize that the term “structured sentence” applies when information is displayed and edited in the appearance of a sentence and when there is structured or coded data underlying the sentence (as opposed to when the sentence is constructed only of unstructured “free-text”). The example shown in FIG. 3 of the specification illustrates this concept of showing information in the appearance of a sentence. Software applications from Oceania and Purkinje, in existence prior to 1999, also illustrated this concept, and used similar terminology to describe it. In contrast, Macrae’s “order node” is a node, represented to the user as a graphical icon contained within a workflow process flow diagram, as illustrated clearly in FIG. 3 of Macrae. One skilled in the art would not look at Macrae’s FIG. 3 and describe it as “structured sentences”.

Regarding the second aspect of the Examiner’s position, that Macrae’s “order node” exists separately from Macrae’s concept of workflow, it appears that the Examiner made two arguments: one based on an assertion that the order node exists before the workflow is created, and another based on the assertion that the two are “stored separately”. In my opinion, an accurate interpretation of the claims requires an understanding of the following two distinctions:

- a. Data for a particular customer (also called “instance” data) is not equivalent to “meta data” (also called “template” data or “generic” data)
- b. Data regarding which services are to be ordered is not equivalent to data regarding the sequence of steps required to carry out each order.

On page 28, the Examiner stated that:

“Macrae et al. teaches templates stored for needed services of a particular patient.”

However, the essential concept of a “template” is that it does not represent data “of a particular patient.” The Examiner went on to say:

“An electronic workflow is *later* created by assigning a service plan to a patient and executing the plan to service the patient.”

However, a “service plan” is defined to be already patient-specific, and therefore would not be assigned to a patient. Taking these two sentences together, it appears that the Examiner equated Macrae’s concept of a “template” (shown at label L in the figure), which does not correspond to any particular customer, with the concept of a “service plan” (shown at label B in the figure), which is specific to particular customer.

The Examiner’s phrase “workflow is *later* created” appears to be an assertion that Macrae’s concept of an order node is separate from Macrae’s concept of workflow because the order node exists before the workflow is ever created. The term “order *node*” suggests to me that it is not separate from the workflow process flow diagram. Furthermore, the Macrae patent includes specific language that defines the concept of an order node as being “contained” within a care plan template (see Column 6, Lines 9-11). Still furthermore, Macrae described the process of adding an order node to a template (Column 8, Line 52-53 and FIG. 9), and subsequently naming the order node (Column 9, Lines 13-26), and adding the orders to the order node (Column 10, Lines 1-27). It seems to me that only *after* the template is created (already in the form of a workflow process flow diagram), can that template be assigned to an individual patient. Only at the time the template is assigned to an individual patient are the orders contained within that template assigned or associated with that individual patient. Macrae went on to describe the process of adding additional orders to an existing care plan for an individual patient (Column 21, Lines 18-37). As with the process of creating a template, this process involves creation of order nodes and associated orders inside a previously-existing

workflow process flow diagram. Therefore, I respectfully disagree with the Examiner's apparent assertion that Macrae anticipates order nodes that exist before the workflow is created.

The Examiner went on to further interpret Macrae (middle of page 28):

"The executing workflow and the service plan are stored separately in the system and are thus separate and distinct entities."

This appears to be an assertion that Macrae's concept of a service plan and Macrae's concept of workflow are separate because they are "stored separately in the system". However, I could not find anywhere in Macrae where the terms "executing workflow" or "service plan" are used, nor could I find any description of service plan data and workflow data being stored separately or in any particular location.

Regarding the third aspect of the Examiners position, that Macrae anticipates the creation of a separate workflow for each order, the Examiner interprets Macrae as follows (middle of page 28):

"For example, if the stored strep? Plan was assigned to Jim Sanders, a workflow process instance would be vitals."

A person skilled in the art would recognize that in the example sited, the "workflow process instance" corresponds to the entire care plan for Jim Sanders (corresponding to label J in the figure). In this context, the word "instance" is equivalent to saying "one particular workflow process assigned to a particular patient", and is used to distinguish from "meta data" or "templates", which are not patient-specific. In the "Jim Sanders" example in the Macrae specification that was referenced by the Examiner, the workflow process instance contains nodes, including one or more order nodes. One of those order nodes contains an order labeled "vitals" (as shown in FIG 13 of Macrae). In my opinion, to assert that Macrae equates this order to measure the vital signs of the patient with a

workflow process instance, one would need to see a description of a method for creating a workflow process flow diagram containing nodes corresponding to the separate steps required to carry out that vitals order. But I could find no such description in the Macrae patent. In Macrae, the "result node" associated with the order node does include an indicator regarding whether or not the order was done. But a person skilled in the art would not consider this to be a "workflow process instance" for the vitals order.

Finally, regarding the fourth aspect of the Examiner's position, that Macrae's "service plan" exists separately from workflow, the Examiner interpreted Macrae as follows (bottom of page 28):

"Specifically, when the service plan is assigned to a patient, the service plan remains in the saved templates of the system and a specific instance of the workflow is stored in association with the patient for which it is executing."

Again, the Examiner is using the term "service plan" in a manner which implies that it is meta data (i.e. a template), rather than patient-specific data. As clearly defined within both the specification and claims, the term "service plan" refers to data that is patient-specific. For example, claim 1 includes the step of "creating the *service plan*, the service plan including a plurality of structured sentences for each of a plurality of specific needs of *a particular customer...*" In reference to the figure above, the Examiner's observation that Macrae's templates (label L) are separate from Macrae's patient-specific care plans (label J) is not evidence that Macrae anticipated a customer-specific service plan in the form of structured sentences (label B) separate from the workflow instances used to managed the execution of each structured sentence for service (label C).

6. Analysis of Examiner's Rejection of Claim 26, regarding Population Care Management.

The Examiner pointed out (top of page 30) that the amended claim 26 does not include a limitation that the process of updating a predetermined plurality of existing service plans

occurs *automatically*, even though such a limitation is included in the specification. It is my understanding that, in response to this observation by the Examiner, claim 26 has been further amended so that it more completely aligns with the specification by clarifying that the step of adding new structured sentences for service and the step of adding workflow process instances both occur automatically.

7. Analysis of Examiner's Rejection of Claim 40, regarding Feedback on Alert Appropriateness.

The Examiner concluded that, in light of Macrae and Brown, claim 40 would have been obvious. Macrae described alerts, but did not describe any method for collecting any type of feedback data regarding alerts. While Brown did describe collecting feedback data associated with alerts, it does this for a different type of user, involving different type of feedback data, without aggregation across users, and using the feedback data to modify different types of data.

- **Different Type of Users.** Brown described a system used by patients (the subjects of the care plan), rather than a system used by clinicians (the authors of a care plan).
- **Different Type of Feedback Data.** In Brown, the feedback obtained from the user is in regards to "patient compliance, symptomatology, possible drug interactions or side effects of medication if required by the treatment regimen, and other facts relevant to evaluation and possible modification of the *treatment regimen*." In contrast, the feedback defined in ACPMS is in regards to the clinician's assessment of the appropriateness of the alert message itself. Despite the assertion of the Examiner, we found no reference in Brown to the capture of data regarding the appropriateness of the alert message.
- **Different Aggregation.** In Brown, the feedback obtained is evaluated by the server for a single patient (see Column 5, Line 60), rather than being aggregated (grouped) across all users.
- **Different Type of Data Modified based on Feedback Data.** In Brown, the feedback obtained is evaluated for the purpose of automated revision of treatment regimen (the care plan for an individual patient), based on a previously prepared

"protocol" that defines the logic for such care plan revisions. In contrast, in ACPMS, the feedback obtained is evaluated for the purpose of identifying which alert messages are frequently designated as "inappropriate" by clinicians, in order to provide data suggesting which alert messages may need to be manually revised or deleted. In other words, Brown uses feedback data to modify patient-specific data, while ACPMS uses the feedback data to modify metadata.

In light of these essential differences, it seems to me that Brown has little relevance to claim 40. The fact that Brown described capturing some type of feedback data from some type of computerized alert for some application in the health care field is not sufficient to motivate a person skilled in the art to combine Macrae and Brown or to otherwise make obvious the material of claim 40. Furthermore, I am not aware of any system or planned system that utilized this method back in 1999, nor any system or planned system that utilizes this method today. It is my understanding that since claim 40 is ultimately subordinate to claim 1, a rejection of claim 40 would require an assertion that it would be obvious to use such a method even considering the further limitations of claim 1, with a care plan being comprised of structured sentences and the creation of an electronic workflow for each structured sentence for service in the care plan to assist in carrying out the steps required to provide each needed service. Therefore, I respectfully disagree with the Examiner's conclusion regarding the obviousness of claim 40.

8. Analysis of Examiner's Rejection of Claims 69 and 70, regarding Workflow to Route Draft Care Plans for Review and Revision by Members of an Interdisciplinary Team of Clinicians.

The Examiner acknowledged (in the bottom of page 30) that Macrae does not expressly disclose the interdisciplinary team of clinicians creating the structured sentences (which exist in a service plan for a particular patient). The Examiner argued that, because it is old and well known that interdisciplinary teams of clinicians "create the acceptable medical procedures that are used by the medical community", it would be obvious to have the interdisciplinary team build the structured sentences. It is true that, in the

medical field, there is a long tradition of employing interdisciplinary teams of clinicians to develop clinical practice guidelines, practice standards and otherwise to define practices that are to be considered acceptable by the medical community in general. But it is not at all clear to me why this observation is relevant to the question of whether it would be obvious to use a workflow automation process as a method of routing a draft care plan to members of an interdisciplinary team of clinicians to review and revise the care plan of a particular patient. As explained in the specification, it is old and well-known in the medical field for an interdisciplinary team of clinicians to have a face-to-face meeting (such as "tumor board" meetings in a cancer center) to exchange ideas regarding the care of a few selected patients. But I know of no existing or proposed software application intended to electronically route a draft of an electronic care plan for review and revision by such an interdisciplinary team, with or without the use of workflow automation technology – even today, much less in 1999. Furthermore, it is my understanding that, since claims 69 and 70 are ultimately subordinate to claim 1, a rejection of claims 69 and 70 would require an assertion that it would be obvious to use such a method even considering the further limitations of claim 1, with a draft care plan being comprised of structured sentences and the creation of an electronic workflow for each structured sentence for service in the care plan to assist in carrying out the steps required to provide each needed service. Therefore, I respectfully disagree with the Examiner's conclusion regarding the obviousness of claims 69 and 70.

CONCLUSION

9. Based on the foregoing, I respectfully submit that the Examiner's understanding of the scope and meaning of claims 1, 3, 26, 30, 40, 41, 69 and 70 in U.S. Patent Application No. 09/427,149 is incorrect, and thus her application of these claims to the prior art discussed above in support of her rejections is also incorrect. However, I do believe that this Declaration will shed light on these issues and give guidance to the Examiner in her consideration of this matter from the perspective of one of ordinary skill in the health care information technology industry art.

10. I hereby declare that I have reviewed and understand, to the best of my ability, any documents mentioned herein.

11. I hereby declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment or both under Section 1091 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the present application and any patent issuing thereon.

By: Richard E. Ward
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Date: APRIL 15, 2005

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